

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

STATE OF WISCONSIN

By Attorney General Brad D. Schimel, et al.,

Plaintiffs

v.

INDIVIOR INC. f/k/a RECKITT  
BENCKISER PHARMACEUTICALS, INC.;  
RECKITT BENCKISER HEALTHCARE  
(UK) LTD.; INDIVIOR PLC; and  
MONOSOL RX, LLC,

Defendants

Civ. A. No. 16-cv-5073

IN RE: SUBOXONE (BUPRENORPHINE  
HYDROCHLORIDE AND NALOXONE)  
ANTITRUST LITIGATION

MDL No. 2445

Civ. A. No. 13-md-2445

THIS DOCUMENT APPLIES TO:  
ALL ACTIONS

**INDIVIOR INC.'S ANSWER TO PLAINTIFF STATES'  
AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL**

For its Answer and Defenses to Plaintiff States' Amended Complaint and Demand for Jury Trial (No. 16-cv-5073, Dkt. No. 119) ("Complaint"), Defendant Indivior Inc. ("Indivior") states as follows:

Indivior denies any and all allegations in the Complaint not specifically admitted in the paragraphs below. Section headings from the Complaint are repeated below solely for ease of reference; by copying or referencing section headings Indivior does not admit or attest to their accuracy.

Indivior's investigation of the above-captioned matters is ongoing. Accordingly, Indivior reserves the right to amend this Answer.

**Nature of the Action**

1. Indivior admits that Plaintiffs have filed this lawsuit, but denies that such an action is well-founded and that Plaintiffs have any basis in fact or in law to maintain this action against Indivior. Indivior otherwise denies the allegations in Paragraph 1 of the Complaint.

2. Indivior admits that medications containing a combination of active ingredients buprenorphine and naloxone may be used for treatment of opiate dependency. Indivior admits that it is engaged in the manufacture and sale of Suboxone, which contains a combination of active ingredients buprenorphine and naloxone and which is indicated for treatment of opiate dependency. Indivior denies the remaining allegations in Paragraph 2 of the Complaint.

3. Indivior denies the allegations in Paragraph 3 of the Complaint.

4. Indivior denies the allegations in Paragraph 4 of the Complaint.

5. Indivior denies the allegations in Paragraph 5 of the Complaint.

6. Indivior denies the allegations in Paragraph 6 of the Complaint.

7. Indivior denies the allegations in Paragraph 7 of the Complaint.

8. Indivior denies the allegations in Paragraph 8 of the Complaint. Moreover, Indivior states that Plaintiffs are not entitled to any of the relief set out in Paragraph 8 of the Complaint.

**Jurisdiction & Venue**

9. Indivior states that jurisdiction is a legal conclusion to which no response is required. Indivior otherwise denies the allegations in Paragraph 9 of the Complaint.

10. Indivior states that venue is a legal conclusion to which no response is required.

**Parties**

11. Indivior Inc. admits that it is a Delaware corporation at the address listed, that it is a wholly-owned indirect subsidiary of Indivior PLC, and that it manufactures and sells Suboxone in the United States. Indivior further admits that it was previously known as Reckitt Benckiser Pharmaceuticals, Inc. Indivior denies the remaining allegations in Paragraph 11 of the Complaint.

12. Paragraph 12 of the Complaint pertains to another Defendant. Indivior lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and on that basis denies them.

13. Indivior admits that Indivior PLC is a British corporation incorporated under the laws of England and Wales at the address alleged in Paragraph 13. Indivior admits that certain assets related to the production of Suboxone were transferred to Indivior PLC as described in the documentation relating to that transaction, which speaks for itself. Indivior denies the remaining allegations in paragraph 13 of the Complaint.

14. Paragraph 14 of the Complaint pertains to another Defendant. Indivior lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of the Complaint and on that basis denies them.

15. Indivior denies the allegations in Paragraph 15 of the Complaint.

16. Paragraph 16 of the Complaint pertains to another Defendant. Indivior lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint, and on that basis denies them. To the extent that the allegations of Paragraph 16 pertain to Indivior, Indivior denies these allegations.

17. Indivior admits that government entities and consumers in the United States purchased or provided reimbursement for Suboxone Film and Suboxone Tablets. Indivior denies the remaining allegations in Paragraph 17 of the Complaint.

18. Paragraph 18 alleges Plaintiffs' legal purpose and basis for this action. To the extent a response is required, Indivior denies that Plaintiffs' action is well-founded and that Plaintiffs have any basis in fact or in law to maintain this action against Indivior.

**Relevant Market**

19. Indivior denies the allegations in Paragraph 19 of the Complaint.

20. Indivior admits that Suboxone is approved by the FDA as a Schedule III drug and that Suboxone contains an opioid antagonist to deter abuse. Indivior admits that methadone is a Schedule II drug, and that federal law limits the circumstances in which methadone can be administered. Indivior admits that it has sold Subutex, that Subutex was indicated to treat opioid dependence, that Subutex did not contain naloxone, and that naloxone is an opioid antagonist that (when co-formulated with buprenorphine) can deter abuse. Indivior further admits that Zubsolv and Bunavail are sold in the United States, that they were approved after the launch of the first generic alternatives to Suboxone Tablets, and that they are not AB-rated to Suboxone Film. Indivior denies the remaining allegations in Paragraph 20 of the Complaint.

21. Indivior denies the allegations in Paragraph 21 of the Complaint.

22. Indivior admits that Suboxone Tablets received FDA "orphan drug status," and that the resulting exclusivity period ended in October 2009. Indivior admits that it began selling Suboxone Film in September 2010. Indivior admits that one or more generic manufacturers of Suboxone Tablets began selling buprenorphine-naloxone products in March 2013; however,

Paragraph 22 is misleading and inaccurate by omitting reference to numerous other competing products. Indivior denies the remaining allegations in Paragraph 22 of the Complaint.

### **Trade and Commerce**

23. Indivior admits that in 2002 it began selling Suboxone Tablets in the United States. Indivior denies the remaining allegations in Paragraph 23 of the Complaint.

24. Indivior states that information relating to its revenues earned from the sale of Suboxone can be found in its financial documents, which speak for themselves. Indivior denies the remaining allegations in Paragraph 24 of the Complaint.

25. Indivior admits that Defendant MonoSol entered into one or more contracts regarding the manufacture of Suboxone Film, MonoSol manufactures all Suboxone Film sold in the United States, and MonoSol has been compensated for its services. Indivior denies the remaining allegations in Paragraph 25 of the Complaint.

### **Factual Background**

#### **I. Generic Drug Approval Process**

26. The allegations in Paragraph 26 of the Complaint set forth legal conclusions to which no response is required. To the extent any response is required, Indivior admits the first sentence of Paragraph 26 of the Complaint; however, Indivior states that the second sentence of Paragraph 26 is true with regard to some new drugs, but is incorrect regarding other new drugs.

27. The allegations in Paragraph 27 of the Complaint set forth legal conclusions to which no response is required. To the extent any response is required, Indivior states that Congress passed the Hatch-Waxman Act in 1984, and that Congress' purposes included encouraging brand drug innovation by providing incentives for companies like Indivior to develop and market innovative new medications such as Suboxone Film. Indivior further states

that the Hatch-Waxman Act contains numerous exclusivity provisions designed to *prevent* the entry of generic drugs in specified circumstances.

28. The allegations in Paragraph 28 of the Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Indivior states that the allegations in Paragraph 28 are true in some circumstances, but are incorrect in other circumstances.

29. The allegations in Paragraph 29 of the Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Indivior states that Paragraph 29 presents a simplified discussion of some of the applicable requirements for approval of an ANDA.

30. The first sentence of Paragraph 30 of the Complaint sets forth legal conclusions to which no response is required. To the extent a response is required, Indivior admits that, depending upon the circumstances, oral drugs proven to be pharmaceutically equivalent and bioequivalent (as defined by the FDA) to a branded oral drug may receive an AB-rating from the FDA. As to the remaining allegations in Paragraph 30 of the Complaint, Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

31. Indivior admits that the FDA publishes a list of approved drugs and their therapeutic equivalents in the FDA's "Orange Book." Indivior states that listings in FDA publications speak for themselves.

32. Paragraph 32 of the Complaint set forth legal conclusions to which no response is required. Furthermore, as to the allegations in Paragraph 32 of the Complaint regarding state-level pharmaceutical regulations and practice, and regarding the terms of "most health plans,"

Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

## **II. Suboxone's Orphan Drug Designation**

33. Indivior admits that in 2002 it began manufacturing and selling Suboxone Tablets, which contained active ingredients buprenorphine and naloxone, and that Indivior did not claim that this product was protected by patents covering the two active ingredients. As to the remaining allegations in Paragraph 33 of the Complaint, Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

34. Indivior admits that Suboxone Tablets received a seven-year period of “orphan drug” exclusivity from the FDA. Indivior denies the remaining allegations of Paragraph 34 of the Complaint.

35. The allegations in Paragraph 35 of the Complaint set forth legal conclusions to which no response is required.

36. Indivior admits that it submitted requests for “orphan drug” status for Suboxone Tablets to which the FDA responded. Indivior states that Indivior's submissions and the FDA's responses concerning Suboxone Tablets, as well as the contents thereof, speak for themselves.

37. Indivior admits that Suboxone Tablets were approved in 2002, that FDA had previously designated them to be “orphan drugs,” and that orphan drug exclusivity expired on October 8, 2009. Indivior denies the remaining allegations in Paragraph 37 of the Complaint.

38. Indivior admits that Suboxone Tablets obtained “orphan drug designation” from the FDA. Moreover, Indivior states that information relating to its earnings for the sale of Suboxone Tablets in 2010 can be found in Indivior's financial documents, which speak for themselves. Indivior denies the remaining allegation in Paragraph 38 of the Complaint.

### **III. Allegations Regarding “Reckitt’s Product-Hopping Scheme”**

#### **A. Suboxone Tablet Market Share Threatened by Generic Entry**

39. Indivior denies the allegations in Paragraph 39 of the Complaint.

40. The allegations set out in Paragraph 40 of the Complaint appear to relate to drug products that Indivior has never sold. As such, Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

41. The allegations set out in Paragraph 41 of the Complaint appear to relate to drug products that Indivior has never sold. As such, Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

42. Paragraph 42 of the Complaint appears to quote annual reports issued by an entity that is no longer affiliated with Indivior, and appears to relate to that entity’s state of mind. As such, Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

43. The allegations in Paragraph 43 of the Complaint set forth legal conclusions to which no response is required.

44. Indivior denies the allegations in Paragraph 44 of the Complaint.

45. Indivior denies the allegations in Paragraph 45 of the Complaint.

#### **B. Suboxone Film Enters the Market**

46. Indivior admits that it contacted FDA regarding a new drug application for Suboxone Film. Indivior further admits that it worked with MonoSol to develop and manufacture Suboxone Film. Indivior denies the remaining allegations in Paragraph 46 of the Complaint.

47. Indivior denies the allegations in Paragraph 47 of the Complaint.



48. Indivior denies the allegations in Paragraph 48 of the Complaint.

49. Indivior admits that Defendant MonoSol has been compensated for its services in connection with the development and/or manufacture of Suboxone Film. Indivior denies the remaining allegations in Paragraph 49 of the Complaint.

50. Indivior denies the allegations in Paragraph 50 of the Complaint.

51. Indivior admits that MonoSol applied for patent 8,017,150, and that FDA listed this patent in the “Orange Book.”

52. Indivior admits that FDA listed the three specified patents in the Orange Book. As to the allegations regarding lawsuits involving Indivior and MonoSol, the pleadings, filings, and public record materials regarding those lawsuits speak for themselves. Indivior denies the remaining allegations in Paragraph 52 of the Complaint.

53. Indivior admits that it met with MonoSol and the FDA regarding approval for the manufacture and sale of Suboxone Film. Indivior denies the remaining allegations in Paragraph 53 of the Complaint.

54. As to the allegations in Paragraph 54 of the Complaint relating to MonoSol, Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them. As to the allegations in Paragraph 54 of the Complaint relating to Indivior, Indivior denies them.

55. Indivior admits the allegations in Paragraph 55 of the Complaint.

56. Paragraph 56 of the Complaint states a legal conclusion, to which no response is required. To the extent a response is required, Indivior admits that generic tablet products are not AB-rated to Suboxone Film, and that patients prescribed Suboxone Film should not be forced

to accept a product that they do not want and that their doctors did not prescribe. Indivior denies the remaining allegations in Paragraph 56 of the Complaint.

57. Indivior admits that in August 2009, the FDA stated that it would not approve Indivior's New Drug Application for Suboxone Film without additional amendments. Indivior states that FDA's stated reasons for its actions are found in FDA's Action Letter and related FDA documents, which speak for themselves. Indivior denies the remaining allegations in Paragraph 57 of the Complaint.

58. The allegations in Paragraph 58 of the Complaint set forth legal conclusions to which no response is required. To the extent that a response is required, Indivior admits that the FDA Amendments Act of 2007 authorizes the FDA to require REMS programs under the conditions set out in that Act (as amended).

59. Indivior admits that it submitted a revised REMS to the FDA regarding Suboxone Film. Indivior denies the remaining allegations in Paragraph 59 of the Complaint.

60. Admitted.

61. The allegations in Paragraph 61 relate to Defendant MonoSol. Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

62. Indivior denies the first sentence of Paragraph 62 of the Complaint. FDA's stated basis for its approval of Suboxone Film is set out in the documentation FDA created in connection with that approval; these documents speak for themselves. Indivior admits that the words "clinically insignificant" appear in the NDA, but the Complaint uses these words in a misleading manner. Indivior admits that Suboxone Film and Suboxone Tablets were approved

for the same strengths until August 2012, when FDA approved additional strengths of Suboxone Film. Indivior denies the remaining allegations in Paragraph 62 of the Complaint.

63. Indivior denies the allegations in Paragraph 63 of the Complaint.

64. Indivior denies the allegations in Paragraph 64 of the Complaint.

65. Indivior denies the first sentence of Paragraph 65 of the Complaint. Documents written by FDA contain the words quoted in following the second sentence of Paragraph 65 of the Complaint, but the Complaint uses these quotes in a misleading manner. Indivior denies the remaining allegations in Paragraph 65 of the Complaint.

66. Indivior admits that a document written by the FDA contains the words quoted in the first sentence of Paragraph 66 of the Complaint, but the Complaint uses this quote in a misleading manner. Indivior denies the remaining allegations in Paragraph 66 of the Complaint.

67. Indivior admits that a document written by the FDA contains the words quoted in the second sentence of Paragraph 67 of the Complaint, but the Complaint uses this quote in a misleading manner. Indivior denies the remaining allegations in Paragraph 67 of the Complaint.

68. Indivior denies the allegations in Paragraph 68 of the Complaint.

**C. Allegations That “Reckitt Converts the Market from Tablets to Film”**

69. Indivior denies the allegations in Paragraph 69 of the Complaint.

70. Indivior denies the allegations in Paragraph 70 of the Complaint.

71. The allegations in Paragraph 71 appear to relate to Defendants MonoSol and Reckitt Benckiser Healthcare (UK). Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

72. Indivior denies the allegations in Paragraph 72 of the Complaint.

73. Indivior denies the allegations in Paragraph 73 of the Complaint

74. Indivior admits that it sold Suboxone Film in unit-dose packaging. Indivior denies the remaining allegations in Paragraph 74 of the Complaint.

75. Indivior lacks knowledge regarding the claims on Venebio's websites, and on that basis denies the allegations relating to that website. Indivior denies the remaining allegations in Paragraph 75 of the Complaint.

76. Indivior admits that Suboxone Tablets have been sold in unit-dose packaging outside the United States. Indivior denies the remaining allegations in Paragraph 76 of the Complaint.

77. Indivior admits that it promoted Film through Clinical Liasons, that it communicated regarding the Film product to doctors, payors, and pharmacists, and that Indivior attempted in various ways to try to ensure that Suboxone Film was affordable. Indivior denies the remaining allegations in Paragraph 77 of the Complaint.

78. Indivior denies the allegations in Paragraph 78 of the Complaint.

79. Indivior admits that it adjusted the size of its sales force to market Suboxone Film. Indivior denies the remaining allegations in Paragraph 79 of the Complaint.

80. Indivior denies the allegations in Paragraph 80 of the Complaint.

81. Indivior admits that it issued a press release, which speaks for itself. Indivior denies the remaining allegations in Paragraph 81 of the Complaint.

82. Indivior admits that it submitted a Citizen Petition to FDA; this petition speaks for itself. Indivior denies the remaining allegations in Paragraph 82 of the Complaint.

83. Indivior admits that it provided a patient assistance program, and Indivior also admits that it created a program called "Here to Help." Indivior denies the remaining allegations in Paragraph 83 of the Complaint.

84. Indivior admits that it provided discounts and rebates in order to try to make Suboxone Film affordable for patients. Indivior further admits that at various times it increased the Wholesaler Acquisition Cost of its products, including Suboxone Tablets. Indivior denies the remaining allegations in Paragraph 84 of the Complaint.

85. Indivior admits that it engaged in business communications with MonoSol regarding the costs and pricing for the manufacture and sale from MonoSol to Indivior of Suboxone Film. Indivior denies the remaining allegations in Paragraph 85 of the Complaint.

86. Indivior denies the allegations in Paragraph 86 of the Complaint.

87. Indivior denies the allegations in Paragraph 87 of the Complaint.

88. Indivior admits that it stopped selling Suboxone Tablets in March 2013. Indivior denies the remaining allegations in Paragraph 88 of the Complaint.

#### **IV. Allegations That “Reckitt Delays Generic Entry”**

89. Indivior admits that orphan drug exclusivity expired in 2009. Indivior further admits that FDA approved generic buprenorphine-naloxone tablets in February 2013. The allegations concerning when (unspecified) ANDAs were first filed are outside of Indivior’s knowledge, and on that basis Indivior denies these allegations. Indivior denies the remaining allegations in Paragraph 89 of the Complaint.

90. Indivior admits it submitted a REMS for Suboxone Tablets that the FDA approved in December 2011. Allegations regarding the status of competitors’ ANDA filings are outside of Indivior’s knowledge, and on that basis Indivior denies these allegations. Indivior denies the remaining allegations in Paragraph 90 of the Complaint.

91. Indivior admits that in January 2012 FDA pressured Indivior into participating in discussions regarding a potential shared REMS. The second and third sentences of Paragraph 91

of the Complaint appear to relate to REMS programs for products that Indivior has never sold; as such these allegations are outside of Indivior's knowledge, and on that basis Indivior denies these allegations. The "Buprenorphine Products Manufacturers Group" was comprised of different companies at different times, but has included the manufacturers listed. Indivior denies the remaining the allegations in Paragraph 91 of the Complaint.

92. The allegations in Paragraph 92 of the Complaint set forth legal conclusions to which no response is required. To the extent any response is required, Indivior denies these allegations.

93. Indivior denies the allegations in Paragraph 93 of the Complaint.

94. Competing manufacturers in the Buprenorphine Products Manufacturers Group made a number of false accusations in communications with FDA; these communications speak for themselves. Indivior denies the remaining allegations in Paragraph 94 of the Complaint.

95. Indivior denies the allegations in Paragraph 95 of the Complaint.

96. Indivior denies the allegations in Paragraph 96 of the Complaint.

97. Indivior denies the allegations in Paragraph 97 of the Complaint.

98. Indivior denies the allegations in Paragraph 98 of the Complaint.

99. The allegations in Paragraph 99 of the Complaint set forth legal conclusions to which no response is required.

100. The allegations in Paragraph 100 of the Complaint set forth legal conclusions to which no response is required.

101. Indivior denies the allegations in Paragraph 101 of the Complaint.

102. Indivior admits that in September 2012, Indivior filed a Citizen Petition requesting the FDA "refrain from approving any buprenorphine drug application ... for opioid

dependence treatment until the Food and Drug Administration (‘FDA’) considers whether such application includes adequate measures to ensure the safe use of buprenorphine, and require all approved applications to contain the same safeguards.” Indivior denies the remaining allegations in Paragraph 102 of the Complaint.

103. Indivior admits that on or about September 25, 2012, Indivior announced that it would be voluntarily discontinuing the supply of Suboxone Tablets in the United States.

Indivior denies the remaining allegations in Paragraph 103 of the Complaint.

104. Indivior denies the allegations in Paragraph 104 of the Complaint.

105. Indivior denies the allegations in Paragraph 105 of the Complaint.

106. Indivior denies the allegations in Paragraph 106 of the Complaint.

107. Indivior denies the allegations in Paragraph 107 of the Complaint.

108. Indivior admits that the FDA resolved the Citizen Petition on February 22, 2013.

Indivior denies the remaining allegations in Paragraph 108 of the Complaint.

109. FDA’s stated basis for its resolution of Indivior’s Citizen Petition is contained in FDA’s formal response, which speaks for itself. Indivior denies the remaining allegations in Paragraph 109 of the Complaint.

110. FDA’s formal response to the Citizen Petition indicates that, in response to accusations levied by Indivior’s competitors, FDA refused to find that the petition was submitted with the primary purpose of delaying the approval of generic products. However, FDA referred “this matter” to the Federal Trade Commission because FDA lacked the institutional competence to investigate allegations of anticompetitive conduct.

111. Indivior denies the allegations in Paragraph 111 of the Complaint.

112. Indivior denies the allegations in Paragraph 112 of the Complaint.

113. Indivior denies the allegations in Paragraph 113 of the Complaint.

114. Admitted.

115. Indivior admits that in March 2013 generic buprenorphine-naloxone products became available for purchase, and that at the time the vast majority of physicians and patients preferred Suboxone Film to Suboxone Tablets. Indivior denies the remaining allegations in Paragraph 115 of the Complaint.

#### **Effects on Competition**

116. The allegations set out in Paragraph 116 of the Complaint appear to relate to drug products that Indivior has never sold. As such Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

117. The allegations set out in Paragraph 117 of the Complaint appear to relate to drug products that Indivior has never sold. As such Indivior lacks knowledge or information sufficient to form a belief as to their truth and on that basis denies them.

118. Indivior denies the allegations in Paragraph 118 of the Complaint.

119. Indivior denies the allegations in Paragraph 119 of the Complaint.

120. Indivior denies the allegations in Paragraph 120 of the Complaint.

121. Indivior denies the allegations in Paragraph 121 of the Complaint.

122. Indivior denies the allegations in Paragraph 122 of the Complaint.

123. Indivior denies the allegations in Paragraph 123 of the Complaint.

#### **Injury**

124. Indivior denies the allegations in Paragraph 124 of the Complaint.

125. Indivior denies the allegations in Paragraph 125 of the Complaint.

126. Indivior denies the allegations in Paragraph 126 of the Complaint.



127. Indivior denies the allegations in Paragraph 127 of the Complaint.

128. Indivior denies the allegations in Paragraph 128 of the Complaint.

129. Indivior denies the allegations in Paragraph 129 of the Complaint.

130. Indivior denies the allegations in Paragraph 130 of the Complaint.

**Count I: Monopolization under Sherman Act § 2 Against Reckitt Defendants**

131. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

132. Indivior denies the allegations in Paragraph 132 of the Complaint.

133. Indivior denies the allegations in Paragraph 133 of the Complaint.

134. Indivior denies the allegations in Paragraph 134 of the Complaint.

135. Indivior denies the allegations in Paragraph 135 of the Complaint.

136. Indivior denies the allegations in Paragraph 136 of the Complaint.

137. Indivior denies the allegations in Paragraph 137 of the Complaint.

138. Indivior denies the allegations in Paragraph 138 of the Complaint.

**Count II: Attempted Monopolization under Sherman Act § 2 Against Reckitt Defendants**

139. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

140. Indivior denies the allegations in Paragraph 140 of the Complaint.

141. Indivior denies the allegations in Paragraph 141 of the Complaint.

142. Indivior denies the allegations in Paragraph 142 of the Complaint.

143. Indivior denies the allegations in Paragraph 143 of the Complaint.

144. Indivior denies the allegations in Paragraph 144 of the Complaint.

**Count III: Conspiracy to Monopolize under Sherman Act § 2 Against All Defendants**

145. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

146. Indivior denies the allegations in Paragraph 146 of the Complaint.

147. Indivior denies the allegations in Paragraph 147 of the Complaint.

148. Indivior denies the allegations in Paragraph 148 of the Complaint.

149. Indivior denies the allegations in Paragraph 149 of the Complaint.

150. Indivior denies the allegations in Paragraph 150 of the Complaint.

151. Indivior denies the allegations in Paragraph 151 of the Complaint.

152. Indivior denies the allegations in Paragraph 152 of the Complaint.

153. Indivior denies the allegations in Paragraph 153 of the Complaint.

154. Indivior denies the allegations in Paragraph 154 of the Complaint.

155. Indivior denies the allegations in Paragraph 155 of the Complaint.

156. Indivior denies the allegations in Paragraph 156 of the Complaint.

157. Indivior denies the allegations in Paragraph 157 of the Complaint.

158. Indivior denies the allegations in Paragraph 158 of the Complaint.

**Count IV: Illegal Restraint of Trade under Sherman Act § 1 Against All Defendants**

159. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

160. Indivior denies the allegations in Paragraph 160 of the Complaint.

161. Indivior denies the allegations in Paragraph 161 of the Complaint.

162. Indivior denies the allegations in Paragraph 162 of the Complaint.

163. Indivior denies the allegations in Paragraph 163 of the Complaint.

164. Indivior denies the allegations in Paragraph 164 of the Complaint.

165. Indivior denies the allegations in Paragraph 165 of the Complaint.

**Count V: State Law Claims Against Reckitt and MonoSol Defendants**

**Alabama**

166. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

167. Indivior denies the allegations in Paragraph 167 of the Complaint.

**Alaska**

168. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

169. Indivior denies the allegations in Paragraph 169 of the Complaint.

170. Indivior denies the allegations in Paragraph 170 of the Complaint.

**Arkansas**

171. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

172. Indivior denies the allegations in Paragraph 172 of the Complaint.

**California**

173. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

174. Indivior denies the allegations in Paragraph 174 of the Complaint.

175. Indivior denies the allegations in Paragraph 175 of the Complaint.

**Colorado**

176. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

177. Indivior denies the allegations in Paragraph 177 of the Complaint.

**Connecticut**

178. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

179. Indivior denies the allegations in Paragraph 179 of the Complaint.

180. Indivior denies the allegations in Paragraph 180 of the Complaint.

181. Indivior denies the allegations in Paragraph 181 of the Complaint.

182. Indivior denies the allegations in Paragraph 182 of the Complaint.

**Delaware**

183. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

184. Indivior denies the allegations in Paragraph 184 of the Complaint.

185. Indivior denies the allegations in Paragraph 185 of the Complaint.

**District of Columbia**

186. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

187. Indivior denies the allegations in Paragraph 187 of the Complaint.

188. Indivior denies the allegations in Paragraph 188 of the Complaint.

**Florida**

189. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

190. Indivior denies the allegations in Paragraph 190 of the Complaint.

191. Indivior denies the allegations in Paragraph 191 of the Complaint.

192. Indivior denies the allegations in Paragraph 192 of the Complaint.

**Georgia**

193. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

194. Indivior denies the allegations in Paragraph 194 of the Complaint.

**Hawaii**

195. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

196. Indivior denies the allegations in Paragraph 196 of the Complaint.

197. Indivior denies the allegations in Paragraph 197 of the Complaint.

**Idaho**

198. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

199. Indivior denies the allegations in Paragraph 199 of the Complaint.

200. Indivior denies the allegations in Paragraph 200 of the Complaint.

201. Indivior denies the allegations in Paragraph 201 of the Complaint.

**Illinois**

202. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

203. Indivior denies the allegations in Paragraph 203 of the Complaint.

204. Indivior denies the allegations in Paragraph 204 of the Complaint.

**Iowa**

205. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

206. Indivior denies the allegations in Paragraph 206 of the Complaint.

207. Indivior denies the allegations in Paragraph 207 of the Complaint.

208. Indivior denies the allegations in Paragraph 208 of the Complaint.

209. Indivior denies the allegations in Paragraph 209 of the Complaint.

**Kansas**

210. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

211. Indivior denies the allegations in Paragraph 211 of the Complaint.

**Kentucky**

212. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

213. Indivior denies the allegations in Paragraph 213 of the Complaint.

214. Indivior denies the allegations in Paragraph 214 of the Complaint.

**Louisiana**

215. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

216. Indivior denies the allegations in Paragraph 216 of the Complaint.

217. Indivior denies the allegations in Paragraph 217 of the Complaint.

**Maine**

218. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

219. Indivior denies the allegations in Paragraph 219 of the Complaint.

220. Indivior denies the allegations in Paragraph 220 of the Complaint.

**Maryland**

221. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

222. Indivior denies the allegations in Paragraph 222 of the Complaint.

223. Indivior denies the allegations in Paragraph 223 of the Complaint.

**Massachusetts**

224. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

225. Indivior denies the allegations in Paragraph 225 of the Complaint.

226. Indivior denies the allegations in Paragraph 226 of the Complaint.

227. Indivior denies the allegations in Paragraph 227 of the Complaint.

**Michigan**

228. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

229. Indivior denies the allegations in Paragraph 229 of the Complaint.

230. Indivior denies the allegations in Paragraph 230 of the Complaint.

**Minnesota**

231. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

232. Indivior denies the allegations in Paragraph 232 of the Complaint.

**Mississippi**

233. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

234. Indivior denies the allegations in Paragraph 234 of the Complaint.

235. Indivior denies the allegations in Paragraph 235 of the Complaint.

236. Indivior denies the allegations in Paragraph 236 of the Complaint.

**Missouri**

237. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

238. Indivior denies the allegations in Paragraph 238 of the Complaint.

239. Indivior denies the allegations in Paragraph 239 of the Complaint.

**Nebraska**

240. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.



241. Indivior denies the allegations in Paragraph 241 of the Complaint.

242. Indivior denies the allegations in Paragraph 242 of the Complaint.

**New Hampshire**

243. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

244. Indivior denies the allegations in Paragraph 244 of the Complaint.

245. Indivior denies the allegations in Paragraph 245 of the Complaint.

**New Mexico**

246. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

247. Indivior denies the allegations in Paragraph 247 of the Complaint.

248. Indivior denies the allegations in Paragraph 248 of the Complaint.

**New York**

249. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

250. Indivior denies the allegations in Paragraph 250 of the Complaint.

251. Indivior denies the allegations in Paragraph 251 of the Complaint.

252. Indivior denies the allegations in Paragraph 252 of the Complaint.

**North Carolina**

253. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

254. Indivior denies the allegations in Paragraph 254 of the Complaint.

255. Indivior denies the allegations in Paragraph 255 of the Complaint.

**Ohio**

256. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

257. Indivior denies the allegations in Paragraph 257 of the Complaint.

258. Indivior denies the allegations in Paragraph 258 of the Complaint.

259. Indivior denies the allegations in Paragraph 259 of the Complaint.

260. Indivior denies the allegations in Paragraph 260 of the Complaint.

**Oklahoma**

261. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

262. Indivior denies the allegations in Paragraph 262 of the Complaint.

**Oregon**

263. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

264. Indivior denies the allegations in Paragraph 264 of the Complaint.

265. Indivior denies the allegations in Paragraph 265 of the Complaint.

**Pennsylvania**

266. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

267. Indivior denies the allegations in Paragraph 267 of the Complaint.

268. Indivior denies the allegations in Paragraph 268 of the Complaint.

**Rhode Island**

269. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

270. Indivior denies the allegations in Paragraph 270 of the Complaint.

271. Indivior denies the allegations in Paragraph 271 of the Complaint.

**South Carolina**

272. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

273. Indivior denies the allegations in Paragraph 273 of the Complaint.

274. Indivior denies the allegations in Paragraph 274 of the Complaint.

**Tennessee**

275. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

276. Indivior denies the allegations in Paragraph 276 of the Complaint.

277. Indivior denies the allegations in Paragraph 277 of the Complaint.

278. Indivior denies the allegations in Paragraph 278 of the Complaint.

279. Indivior denies the allegations in Paragraph 279 of the Complaint.

280. Indivior denies the allegations in Paragraph 280 of the Complaint.

281. Indivior denies the allegations in Paragraph 281 of the Complaint.

282. Indivior denies the allegations in Paragraph 282 of the Complaint.

**Utah**

283. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

284. Indivior denies the allegations in Paragraph 284 of the Complaint.

**Vermont**

285. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

286. Indivior denies the allegations in Paragraph 286 of the Complaint.

**Virginia**

287. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

288. Indivior denies the allegations in Paragraph 288 of the Complaint.

**Washington**

289. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

290. Indivior denies the allegations in Paragraph 290 of the Complaint.

**West Virginia**

291. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

292. Indivior denies the allegations in Paragraph 292 of the Complaint.

293. Indivior denies the allegations in Paragraph 293 of the Complaint.

294. Indivior denies the allegations in Paragraph 294 of the Complaint.

**Wisconsin**

295. Indivior hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

296. Indivior denies the allegations in Paragraph 296 of the Complaint.

297. Indivior denies the allegations in Paragraph 297 of the Complaint.

**Prayer for Relief**

To the extent a response is required to the Prayer for Relief, Indivior denies the allegations contained therein and states that Plaintiffs are not entitled to any of the remedies set out in the Complaint.

**Jury Demand**

298. Indivior acknowledges that Plaintiff States have demanded a trial by jury.

### **INDIVIOR'S AFFIRMATIVE AND OTHER DEFENSES**

Without assuming any burden that it would not otherwise bear, Indivior asserts the following defenses to the Complaint. Further, Indivior reserves all affirmative defenses under Fed. R. Civ. P. 8(c) and any other defenses, at law or in equity, which may now exist or in the future may be available based on discovery and further factual investigation in this case.

#### **First Defense**

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations, and doctrines of laches, waiver, and estoppel. Indivior did not commit any act, such as fraudulent concealment, that could render these defenses inapplicable.

#### **Second Defense**

Any and all of Indivior's actions alleged by Plaintiffs were lawful, justified, procompetitive, and carried out in furtherance of Indivior's legitimate business interests.

#### **Third Defense**

To the extent Plaintiffs' claims are based in whole or in part on Indivior's petitioning activity, Plaintiffs' claims are barred by the immunity conferred on Indivior by the First Amendment of the United States Constitution and the *Noerr* doctrine.

#### **Fourth Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered injury proximately caused by any conduct of Indivior and/or has not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

**Fifth Defense**

Due to the absence of damages to Plaintiffs or other market participants, Plaintiffs' demands for disgorgement of profits, unjust enrichment, penalties, and fines are disproportionate and in violation of the Due Process Clause.

**Sixth Defense**

Plaintiffs' claims are barred, in whole or in part, because the acts or omissions of Indivior did not substantially lessen competition through the exercise of market power in any properly defined market.

**Seventh Defense**

Plaintiffs' claims are barred, in whole or in part, because Indivior's alleged conduct was unilateral, reasonable, and based on independent, legitimate safety and business justifications.

**Eighth Defense**

Plaintiffs are not entitled to any form of preliminary or permanent injunctive relief.

**Ninth Defense**

Plaintiffs cannot recover from Indivior to the extent that any person sustained damages, as such damages were caused, at least in part, by the actions of Plaintiffs.

**Tenth Defense**

Plaintiffs failed to state a claim for relief.

**Eleventh Defense**

The statutes and other causes of action relied upon by Plaintiffs do not permit the remedies they seek, including disgorgement of profits, restitution, or unjust enrichment.

**PRAYER FOR RELIEF**

WHEREFORE, Indivior prays for relief as follows:

- (a) That the Complaint against Indivior be dismissed in its entirety, with prejudice, and that the Plaintiffs take nothing.
- (b) That Indivior be awarded its attorneys' fees and costs and expenses of the suit; and
- (c) That the Court award such other and further relief as the Court deems just and proper.

Dated: September 28, 2017

Respectfully submitted,

/s/ Jonathan Berman

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*Counsel for Defendant  
Indivior Inc.*



**CERTIFICATE OF SERVICE**

I hereby certify that on the 28th day of September 2017, I electronically filed the foregoing ANSWER TO PLAINTIFF STATES' AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL with the Clerk of the Court using the CM/ECF System which will then send a notification of such filing (NEF) to all counsel of record.

/s/ Mark R. Lentz

Mark R. Lentz

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